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	Abstract	**Purpose:** Osteoporosis remains a major public health concern, considering its high prevalence along with its association with osteoporotic fractures. It imposes a heavy burden on the society worldwide as the population ages. This paper aims to provide a brief review on Iranian multicenter osteoporosis studies (IMOS) studies and provide some recommendations for improvement. **Methods:** IMOS studies were conducted to investigate the prevalence of osteoporosis and related risk factors. This paper provides a general view on the Iranian multicenter osteoporosis studies (IMOS), conducted during last decades. **Results:** The results showed a high prevalence of osteoporosis and vitamin D deficiency in the Iranian population. Although the study protocols were mainly similar, some differences were observed in terms of the study population and design. The protocol of IMOS-3 was modified to overcome the setbacks noted in the previous studies; however, it was implemented in two cities with noticeably different socioeconomic and geographical characteristics from five cities where the first phase was conducted, resulting in different lifestyles and habits. Although previous IMOS studies have raised major concerns regarding the high prevalence of osteoporosis and vitamin D deficiency, interpretation should be made with caution given the differences, especially in the surveyed cities. Such discrepancies cause problems in trend analysis, and nationally representative samplings are preferably needed to correctly compare the prevalence of osteoporosis and related risk factors.

		Conclusions: Considering the aging population and the importance of osteoporosis and its complication, developing a standard surveillance system to obtain valid and nationally representative estimates is recommended.
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REVIEW ARTICLE

Iranian Multicenter Osteoporosis Studies (IMOS) during last decade: rationale, main findings, lessons learned and the way forward

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Abstract

Purpose Osteoporosis remains a major public health concern, considering its high prevalence along with its association with osteoporotic fractures. It imposes a heavy burden on the society worldwide as the population ages. This paper aims to provide a brief review on Iranian multicenter osteoporosis studies (IMOS) studies and provide some recommendations for improvement.

Methods IMOS studies were conducted to investigate the prevalence of osteoporosis and related risk factors. This paper provides a general view on the Iranian multicenter osteoporosis studies (IMOS), conducted during last decades.

Results The results showed a high prevalence of osteoporosis and vitamin D deficiency in the Iranian population. Although the study protocols were mainly similar, some differences were observed in terms of the study population and design. The protocol of IMOS-3 was modified to overcome the setbacks noted in the previous studies; however, it was implemented in two cities with noticeably different socioeconomic and geographical characteristics from five cities where the first phase was conducted, resulting in different lifestyles and habits. Although previous IMOS studies have raised major concerns regarding the high prevalence of osteoporosis and vitamin D deficiency, interpretation should be made with caution given the differences, especially in the surveyed cities. Such discrepancies cause problems in trend analysis, and nationally representative samplings are preferably needed to correctly compare the prevalence of osteoporosis and related risk factors.

Conclusions Considering the aging population and the importance of osteoporosis and its complication, developing a standard surveillance system to obtain valid and nationally representative estimates is recommended.

Keywords Osteoporosis · Iran · Prevalence · Vitamin D deficiency

Introduction

Osteoporosis, characterized by fragile bones, develops gradually and is often diagnosed when a minor fall or light trauma causes bone fracture. Worldwide, approximately one-tenth of women aged 60 and over are affected by osteoporosis [1]. Osteoporosis imposes a heavy burden on the patient and the society. Fractures are the common complications and

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annually, account for a global loss of 5.8 million healthy life years due to disability [2].

According to a study published in 2005, Iran accounts for 12.4% of the total burden of hip fracture in the Middle East. The Disability Adjusted Life Years attributable to hip fracture was estimated at 16,708 years including 8,812 (52.7%) Years of Life Lost and 7,896 (47.3%) Years Lived with Disability [3].

Iran has experienced an upward trend in life expectancy during the past two decades resulted in increasing proportion of the population aged ≥ 60 years [4]. As a result, in parallel with the global trends [5], the country is facing a surge in the number of at-risk population for osteoporosis. The prevalence of osteoporosis at either hip or lumbar site among Iranians aged ≥ 50 years was 22.2% in women and 11.0% in men in 2010. The corresponding values for osteopenia were 59.9% and 50.1%, respectively [6]. Bone loss was also detected in almost 33.0% of women and 31.6% of men younger than 50 years [6, 7]. A recent meta-analysis showed the prevalence of osteoporosis at lumbar spine in Iran to be about 12% in men and 19% in postmenopausal women; however, the values were heterogeneous. For instance, the prevalence in men ranged from 8–22% in 2004 and from 6–31% in 2008 [8]. Some studies have also showed the high prevalence of related risk factors such as vitamin D deficiency [9, 10] and physical inactivity [11] in the Iranian population.

Regarding the preventable nature of osteoporosis and related complications, illustrating a comprehensive picture of the related risk factors and their nation-wide distribution can help pave the way to adopt more effective strategies by policymakers. The Iranian Multicenter Osteoporosis Studies (IMOS) are a group of national studies conducted by the Endocrinology and Metabolism Research Institute affiliated with Tehran University of Medical Sciences, and the Iranian Ministry of Health and Medical Education to establish a foundation for public health interventions.

As we are on the verge of conducting the new round of IMOS, we reviewed the main national surveys on osteoporosis, with a special focus on their study design. In this study we have tried to summarize and present the points and lessons learned from these studies that we believe can help improve future studies to be conducted in this regard.

Material and methods of different phases of the IMOS Studies

The main objectives of the IMOS projects were: (i) to assess the standardized prevalence of osteoporosis and osteopenia, (ii) to determine the age of peak bone mass, and (iii) to determine the prevalence of serum vitamin D deficiency and other osteoporosis risk factors in different urban areas.

The first phase, IMOS-1, was conducted in 2001. A random cluster sampling method was used [2, 12] and a total of 5,339 healthy men and women aged between 20 and 76 years were enrolled from urban areas of five main cities (Tehran, Mashhad, Shiraz, Tabriz, and Bushehr) [13, 14]. The exclusion criteria were having a history of rheumatoid arthritis, type 1 diabetes mellitus, thyroid, parathyroid, adrenal, renal or cardiac diseases, history of infertility, oligomenorrhea, malignancy, malabsorption, long-term immobilization, pregnancy, breastfeeding, and alcoholism as well as taking medications affecting bone metabolism [2, 14].

The second phase, (IMOS-2), was conducted in 2005 in two Iranian cities (Sari and Yazd), using a nearly similar recruitment process and protocol [13]; almost 1400 men and women aged between 20 and 70 years were recruited. Besides the exclusion criteria of IMOS-1, individuals with history of illicit drug use or supplementation (calcium, at least one tablet per day and/or vitamin D, oral consumption during past three months or injection during past year), and professional athletes as well as those with a vertebral fracture or history of any falls leading to fracture and hospitalization in two weeks prior to the study were excluded (unpublished protocol).

In the first two phases of IMOS, from each house, only one person from a randomly defined age range was invited for the study [15]. One fasting blood sample was taken from each participant in his/her place of residence, in winter. Samples centrifuged and serum extraction was done in that city's lab. Then samples were frozen immediately and were sent to the EMRC laboratory for analysis [13].

The third phase, (IMOS-3), was conducted in Arak and Sanandaj in 2011. These two cities were selected because of their considerably different socioeconomic and geographical characteristics, resulting in different lifestyles and habits. Using a one–stage cluster sampling, a total of 2,100 Iranian adults, aged ≥ 20 years were enrolled from urban areas of these two cities. All the adults who met the inclusion criteria in these families and adjacent households, based on the census list, were recruited until 15 individuals were included in each cluster. The interviewers were asked to visit the households in the afternoons, which was a better time for all family members. The individuals, who agreed to sign an informed consent form, were asked to fill a questionnaire at the time of the visit and then referred for laboratory and bone mineral density testing upon the arranged time [16].

The protocol was modified to overcome the setbacks noted in the previous phases [16]. Individuals with any mental/psychological problems, those unable to cooperate with the interviewers, those with a deformity in the spine, hip or lower extremities that would affect BMD results, those who weighed more than 120 kg as well as those who were hospitalized for more than 2 weeks or immobilized for more than 3 consecutive months were excluded. Individuals suffering from infertility, acute/chronic renal failure, advanced liver failure, any kind of cancer, chronic diarrhea, mal-absorption and those

taking any type of vitamin D in the past 6 months were also excluded [16].

Design characteristics of the three IMOS studies were summarized in Table 1.

Measurements

In IMOS-1, the participants completed a questionnaire, mainly collecting information on their life-style (physical activity, sun exposure, diet) along with past medical and drug history. Along with the information gathered in IMOS 1, an additional questionnaire was designed for the female head of household or the oldest woman living in the house in IMOS-3 to assess their knowledge of osteoporosis [16].

Using Dual-energy X-ray Absorptiometry technique, the BMD was measured in IMOS studies [13, 16]. Since the devices were not exactly the same in study centers, sBMD was used to facilitate the conversion and comparability of results between the cities.

Related biochemical parameters were tested in all phases; moreover, in phase 3 whole blood samples were collected for genetic studies and DNA was extracted. Neither the measurement of knowledge on osteoporosis nor the genomic studies were performed in the first two phases of IMOS studies.

Results

The results of IMOS-1 showed that 78.2% of postmenopausal women and 77.3% of men aged 50 years and older had osteopenia or osteoporosis [12]. Comparing the prevalence of osteoporosis in the over 50-year-old population showed a higher prevalence among females (28% in men and 35.2% in women) [12]. As for individuals aged less than 50 years, men showed higher prevalence of bone loss at femoral neck and total hip [17]. In IMOS- III prevalence of osteoporosis in men aged ≥ 50 years and in postmenopausal women were 44% and 37%, respectively [18].

The prevalence of moderate to severe vitamin D deficiency in IMOS-1 was 47.2%, 45.7% and 44.2% in men aged < 50,

Table 1 Design characteristics of the three IMOS studies

	IMOS-I	IMOS-II	IMOS-III
Year	2001	2005	2011
Location	Tehran, Mashhad, Shiraz, Tabriz, and Bushehr	Sari and Yazd	Arak and Sanandaj
Age/Gender	men and women aged between 20 and 76 years	men and women aged between 20 and 70 years	Adults aged ≥ 20 years
Sample size	5339	1400	2100
Measurements	1. Lab data 2. Life-style (physical activity, sun exposure, diet) along with past medical and drug history 3. BMD	1. Lab data 2. life-style (physical activity, sun exposure, diet) along with past medical and drug history 3. BMD	1. Lab data 2. Life-style (physical activity, sun exposure, diet) along with past medical and drug history. 3. knowledge of osteoporosis of the female head of household or the oldest woman living in the house 4. Genetic testing
Inclusion Criteria	Healthy men and women aged between 20 and 76 years from urban area	men and women aged between 20 and 70 years from urban area	aged ≥ 20 years from urban areas
Exclusion Criteria	having a history of rheumatoid arthritis, type 1 diabetes mellitus, thyroid, parathyroid, adrenal, renal or cardiac diseases, history of infertility, oligomenorrhea, malignancy, pregnancy, malabsorption, long-term immobilization, breastfeeding, and alcoholism as well as taking medications affecting bone metabolism	history of illicit drug use or supplementation (calcium, at least one tablet per day and/or vitamin D, oral consumption during past three months or injection during past year), and professional athletes as well as those with a vertebral fracture or history of any falls leading to fracture and hospitalization in two weeks prior to the study.	Individuals with any mental/psychological problems, those unable to cooperate with the interviewers, those with a deformity in the spine, hip or lower extremities that would affect BMD results, those who weighed more than 120 kg as well as those who were hospitalized for more than 2 weeks or immobilized for more than 3 consecutive months were excluded. Individuals suffering from infertility, acute/chronic renal failure, advanced liver failure, any kind of cancer, chronic diarrhea, mal-absorption and those taking any type of vitamin D in the past 6 months

50–60 and ≥ 60 years, respectively. The data from Bushehr were not included due to the heterogeneity of the data. In women of the same age, these values were 54.2%, 41.2% and 37.5%, correspondingly [9]. The highest rate of moderate to severe vitamin D deficiency was noted in Tehran [9, 19]. In IMOS-3, 66.4% of the studied population suffered from vitamin D deficiency. The rate was significantly higher in women (68% vs. 63%, $p = 0.02$). Deficiency was more prevalent in participants aged less than 50 (68% vs. 61%, $p < 0.01$). Prevalence of vitamin D deficiency was higher in women aged less than 50 while in men, the higher prevalence was detected in population aged > 50 years. The difference between prevalence of vitamin D deficiency in men and women was statistically significant (57% vs. 68%, $p < 0.01$). Osteoporosis in either site was detected in 35% of men and 36% of women aged over 50 years (Unpublished data).

The results of logistic regression analysis in IMOS-1 marked age, female sex and menopause as the main risk factors for osteoporosis [2]. As expected, BMD was shown to be significantly positively correlated with weight, height, body mass index (BMI) and waist-to-hip ratio in both genders(all correlations were positive with p-value < 0.05) [20].

The results showed that 81.3% of the female head of household in IMOS-3 had a poor knowledge of different aspects of osteoporosis and its complications. It was also shown that higher level of osteoporosis-related knowledge was associated with an increase in vitamin D intake [21].

Discussion

IMOS studies showed that roughly one-third and half of the Iranian population aged > 50 years suffered from osteoporosis and osteopenia, respectively. The results also showed high prevalence of vitamin D deficiency among Iranians. On the other hand, poor knowledge of the disease was reported among women head of households, who play an important role in the life style of the family including the eating and physical activity habits.

Consistent with IMOS studies, a meta-analysis of the published studies in the Eastern Mediterranean Region showed the prevalence of osteoporosis to be as high as 24.4% (95% CI, 20.4–28.2) in postmenopausal women and men aged ≥ 50 years. The prevalence was significantly higher in 2007–2015 compared with that of 2000–2006 [22]. These figures indicate an urgent need for special attention by health service authorities.

Apart from osteoporosis, IMOS studies were tailored to assess the incidence of osteoporosis-associated risk factors, and their changes over time. In general, to assess the severity of health issues and the effect of intervention, repeated cross-sectional surveys are recommended. Independent samples collected at each round of survey studies are generally perceived as desirable data that can provide harmonized information on the outcome. To maximize comparability, a similar sampling design with standard protocols and questionnaires, consistent definition of the study population, variables and indicators as well as equivalent measurement techniques are highly recommended. These studies are more cost-effective and desirable when marginal probabilities are of interest [23].

Limitations

Although IMOS studies have highlighted the importance of osteoporosis and Vitamin-D deficiency in Iran, and in each phase have tried to address some of the shortcomings of the previous stages, all IMOS studies were conducted in capital cities due to logistic constraints, and thus may not be representative of the urban population of smaller cities or rural areas. This is while 26% of the Iranian population live in rural areas, and so there is scarce information on bone health of rural population (https://www.amar.org.ir/#5538643).

Recommendations and the way forward for the scientific community

- Regarding the high burden of osteoporosis and osteoporotic fractures and the importance of evidence-based policy, the results need to be updated since the last IMOS study was conducted in 2011. The results of prevalence studies are dependent on the study site. For example, according to the STEPS Survey in 2016 [24], the prevalence of smoking in men varied from 20% in South Khorasan to nearly 55% in Qazvin. The prevalence of vitamin D deficiency also varies in different regions of Iran from 33.5% (95%CI: 28.8–38.3) to 80.3 (95%CI: 76.6–84.1) among men and from 31.0 (95%CI: 21.9–40.1) to 91.0 (95% CI: 88.9–93.2) among women [10].
- To overcome the challenge of such heterogeneity, clustering approach is recommended. to have a nationally representative sample, clustering by the potential effective osteoporosis-related factors, such as nutrition, urbanization index, wealth index, physical activity, dairy consumption, etc. should be used. The proposed method guarantees that the sample is well spread in different parts of the country.
- The peak bone age was determined in previous phases of IMOS studies. Considering the main goals of IMOS study in the next phase, which is determining the prevalence and related risk factors in the at-risk population, limiting the survey on the elderly population would be recommended to reduce the sample size and logistic constraints.
- Sarcopenia, defined as reduced muscle mass with limited mobility, is currently considered as an important health issue and suspected older individuals should be screened

for this problem [25]. The muscles and the skeletal systems are closely interconnected as a "hazardous duet," [26] and the combination of osteoporosis and sarcopenia, may increase the probability of falls, leading to fragility fractures [27, 28]. There is no nationally representative information about the prevalence of sarcopenia; however, the prevalence of sarcopenia in 2011 in Tehran was reported to be as high as 20.7% in men and 15.3% in women [29]. Taking into account the common risk factors and complications of osteoporosis and sarcopenia, identifying the prevalence and related risk factors of sarcopenia in the next round of IMOS is recommended.

Point to be considered in designing the national repeated surveys

- Repeated surveys make the opportunity for the trend analysis that summarizes the patterns across time and helps to estimate the current and previous interested variables and their changeability and uncertainties during different period of time. considering the significance of time and associations with other prognostic factors, these studies provide a basis for further study in prediction and projection and also could provide essential recommendations for the policymakers to prioritize the problems for better resource allocations.
- To achieve the stated goals, some critical points should be considered, e.g. survey design adjustment, specify survey sampling units, strata and applying appropriate weights. There is also a need for the identification of necessary variables that requires expert knowledge and a deep literature review. Variable measurements should also be harmonized to better comparison between studies.
- National surveys may impose huge cost to the health system, so using approaches to reduce the study cost is preferable. One of the most recommended design is cluster sampling that reduce the costs, given the predefined accuracy and having the nationally representative data. Clustering could be applied in different ways such as model-based clustering. In this method, using a statistical modeling, a country is divided into different geographical zones; each zone consists of provinces that are similar in terms of the variables related to the interested outcome.

Conclusions

Osteoporosis and osteoporotic fractures impose a heavy burden on health systems worldwide. Understanding the epidemiology of osteoporosis is necessary to develop strategies to reduce its burden. National systematic studies to identify the changes over time are lacking; strengthening osteoporosis surveillance through developing repeated nation-wide surveys are recommended.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest in the authorship or publication of this contribution.

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